

Uni-Gold™ Syphilis Treponemal

20 Tests

Store Kit at +2 to +30°C

REF 1206710

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków

Para outras línguas
Για τις άλλεςλώσσες
Für andra språk
For andre språk



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INTENDED USE

The Trinity Biotech Uni-Gold™ Syphilis Treponemal is a single use rapid immunoassay for the qualitative detection of *Treponema pallidum* (*T. pallidum*) antibodies in human whole blood (venous or fingerstick), serum and plasma. Uni-Gold™ Syphilis Treponemal is intended as an initial screening test or to be used in conjunction with non-treponemal testing and clinical findings to provide serological evidence of Syphilis infection. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

Syphilis is a disease, usually sexually transmitted, caused by the spirochete *T. pallidum*. Infection is systemic from the outset and the disease is characterized by periods of latency, often in excess of twenty years. These features, together with the fact that *T. pallidum* cannot be readily identified by culture methods, mean that serological techniques play a major role in the diagnosis of Syphilis and treatment follow-up.¹ In response to *T. pallidum*, two types of human antibody responses normally result: non-specific (anti-Cardiolipin and various lipoidal molecules) and Syphilis specific (anti-Treponemal antigens).

The procedures most commonly used to screen for syphilis in clinical laboratories are based upon their reaction with non-treponemal lipoidal antigens (the reagin tests). Reagin tests, such as the RPR or VDRL, can be used to test serial dilutions of the serum specimen. The end point values from sequentially obtained serum samples decline following successful treatment until after a period of several months the patient will usually become reagin test non-reactive.

Clinical (serum) specimens reactive in reagin tests are typically confirmed using treponemal tests such as the Microhaemagglutination-*T. pallidum* (MHA-TP/TPHA), *T. pallidum* Particle Agglutination (TPPA) or the Fluorescent Treponemal Antibody-Absorption (FTA-ABS) test. In contrast to the non-treponemal tests, treponemal test reactivity will persist following treatment in approximately 85% of the cases often for the life of the patient.² Any sera giving positive or equivocal results on initial treponemal based assays must be supplemented with a quantitative non-treponemal test (such as RPR or VDRL) to distinguish from active disease and assist in ruling out false positives.

Although MHA-TP/TPHA and FTA-Abs are generally considered reliable, their specificity is limited due to the presence of non-specific antigens in the *T. pallidum* culture preparations. The use of recombinant treponemal antigens results in increased sensitivity and specificity. The antigens detect *T. pallidum* specific IgG, IgM, and IgA; enabling the test to detect antibodies during all stages of infection.

PRINCIPLE OF THE TEST

The Uni-Gold™ Syphilis Treponemal test is based on the binding of recombinant Treponemal antigens specific to anti-treponemal human antibodies. An antigen-antibody-microparticle complex is formed when a positive sample, containing human anti-treponemal immunoglobulins, binds to the recombinant treponemal antigen-red latex microparticle conjugate. This complex flows through the device and binds to a second recombinant treponemal antigen immobilized onto the membrane in the test region of the device. This double antigen sandwich complex forms a visible pink/red band in the test region of the device.

A reactive result is indicated by a pink/red band of any intensity in the test region of the device. A non-reactive result occurs in the absence of detectable levels of anti-treponemal human antibodies in the sample; consequently no visually detectable band develops in the test region of the device.

The control line is a non-specific conjugate complex based system that gives a visible pink/red band in the control region of the device. The control line should always appear in the control region and indicates that the test device is functioning correctly.

REAGENTS

MATERIALS SUPPLIED

- 1206710-D Test devices: 20 pouched devices containing a membrane striped with recombinant treponemal antigens, and pads with dried red latex conjugated to recombinant treponemal antigens.
- 1206710-B Wash Buffer: (3.0 ml) A buffered solution preserved with Sodium Azide.
- 99-8001 Disposable transfer pipettes: 20 disposable pipettes used to add serum/plasma sample.

- 99-8000 Whole blood capillary tubes: 20 capillary tubes used for whole blood fingerstick collection and blood transfer from venipuncture blood tube.
- Package insert

MATERIALS REQUIRED BUT NOT SUPPLIED

- Venous whole blood collection container
- Sterile lance device for fingerstick
- Antiseptic wipes
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves and/or protective clothing
- Adhesive bandages
- Uni-Gold™ Syphilis Treponemal Control (Cat. # 1206711).

STORAGE AND STABILITY

STORAGE REQUIREMENTS

- Store all components at 2-30°C.
- Do not freeze or overheat.
- This product should not be used beyond the expiration date printed on the outer package label.
- The test kits should be kept away from direct sunlight, moisture and heat.

WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic use only.
- For professional use only.
- Directions should be read and followed carefully.
- Test Devices are for single use only. Do not reuse.
- In some situations, a positive result may reflect a previously treated infection.
- In some situations, a negative result can exclude the early onset of the infection.
- Instructions for use should be read and followed carefully.
- Do not use test devices if foil pouches are opened or appear defective.
- Do not use test devices if desiccant pack is missing from the foil pouch.
- Performing the assay outside the run, read times and temperature ranges provided in the Test Procedure section may produce invalid results. Assays not falling within the established time and temperature ranges must be repeated.
- Do not interchange reagents between kits with different lot numbers.
- Microbial contamination of reagents may decrease the accuracy of the assay.
- Use separate pipettes for each sample and control to avoid cross contamination.
- Do not use kits or reagents after the stated expiration date.
- Adequate lighting is required to interpret test results.
- Reagents are provided at the necessary working strength. Do not dilute reagents.
- Treat all materials as if they were infectious and dispose of all material in accordance with local regulation. Liquid waste should be disposed of in a 1% sodium hypochlorite solution or in accordance with local requirements for disposal of infectious material.
- Dilution buffer solution contains <0.1% sodium azide. Sodium azide is toxic if ingested and forms potentially explosive copper and lead azide compounds in waste plumbing lines. Should the reagents come in contact with copper or lead waste plumbing, flush the waste line with large quantities of water to prevent the formation of potentially explosive compounds.

The safety data sheet is available upon request.

WARNING

- Some components of this kit contain < 0.1% sodium azide.
- EUH031: Contact with acid liberates toxic gas.
- H302: Harmful if swallowed.
- H317: May cause an allergic skin reaction.
- H335: May cause respiratory irritation.
- P264: Wash thoroughly with plenty of soap and water after handling.
- P270: Do not eat, drink or smoke when using this product.
- P280: Wear protective gloves / protective clothing / eye protection / face protection.
- P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
- P330: If swallowed, rinse mouth.
- P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.
- P501: Dispose of contents and container in accordance to local, regional, national and international regulations.

SAMPLE COLLECTIONS AND TRANSPORT

- Whole blood samples should be tested immediately. If assays are not run immediately, a whole blood sample may be stored refrigerated (2-8°C) and tested within 8 hours. If testing cannot be carried out within 8 hours of blood sample collection, a plasma or serum sample should be generated and stored accordingly.
- Do NOT freeze whole blood samples.
- If assays are not completed within 8 hours, separated serum/plasma should be refrigerated (2-8°C) up to a maximum of 48 hours. Beyond 48 hours, serum/plasma should be frozen at or below -20°C. Avoid repeated freezing and thawing.
- Whole blood, serum and plasma samples should be refrigerated (2-8°C) during transportation and in compliance with transport regulations of biohazardous agents.
- For venous whole blood collection, qualified personnel using approved aseptic venipuncture techniques should collect a whole blood sample.

QUALITY CONTROL

Good Laboratory Practice (GLP) recommends the use of control specimens to ensure proper device performance at least once daily. Uni-Gold™ Syphilis Treponemal Controls (Cat. # 1206711) are available separately for use only with the Uni-Gold™ Syphilis Treponemal. These controls are used to verify correct device performance, operator procedure and result interpretation. The positive control will produce a reactive test result and the negative control will produce a non-reactive test result (refer to the Interpretation of Results section).

It is recommended that positive and negative controls are run:

- By all new operators performing testing on patient specimens.
- With each new kit lot and whenever a new shipment of test kits is received.
- At periodic intervals as specified in the laboratory Quality Assurance programme.

Uni-Gold™ Syphilis Treponemal Controls must give the expected reactive or non-reactive results. If the test results are not valid repeat the test. Refer to the Uni-Gold™ Syphilis Treponemal Controls package insert (1206711-29EN) for instructions on the use of these reagents. It is the responsibility of each laboratory using the Uni-Gold™ Syphilis Treponemal to establish an adequate quality assurance programme to ensure the performance of the device under its specific locations and conditions of use. Contact Trinity Biotech should unexpected results occur.

Each Uni-Gold™ Syphilis Treponemal device has a built in procedural control that demonstrates assay validity. When a red/pink line appears at the control line position this indicates the device has performed correctly. The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the Interpretation of Results section).

LIMITATIONS

1. Uni-Gold™ Syphilis Treponemal must be used in accordance with the instructions in this package insert to obtain an accurate result.
2. Uni-Gold™ Syphilis Treponemal is specific for detecting *T. pallidum* antibodies in human whole blood, serum or plasma samples. It does not detect *T. pallidum* directly.
3. A negative test result does not exclude the possibility of the presence of *T. pallidum* antibodies and may occur when the antibody level in the sample is below the detection level of the test. Correlation between the amount of antibody in a sample and clinical presentation has not been established.
4. Anti-treponemal antibodies continue to be reactive long after infection (probably for the life of the patient); therefore assays to monitor these analytes should not be used to evaluate a response to therapy, nor in determining relapse or re-infection in a patient.
5. The result from the Uni-Gold™ Syphilis Treponemal cannot be used to derive a relationship between the intensity of the specific visible bands and the occurrence of severity of clinical symptoms. The results obtained must always be interpreted in combination with the clinical evaluation.
6. A positive result does not rule out the presence of another infectious pathogen.
7. An excess of whole blood can cause red blood cells to flow into the read window. This may make it difficult to interpret the test and control lines. In some cases, it may cause conjugate to bind to the test line causing a false positive result. In all cases of excess whole blood, it is necessary to repeat the test with the correct sample volume.
8. Excessive handling of whole blood may cause lysis of the red blood cells and lead to incorrect results.
9. Proper sample collection and processing are essential to achieve optimal performance of the assay. Optimal test results are obtained when samples are tested as soon after collection as possible. Fresh, whole blood should be stored at 2-8°C and tested within 8 hours of collection. If fresh serum or plasma samples cannot be tested within 48 hours, they should be frozen at -20°C or below in a non-defrosting freezer. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

1. Ensure all samples are well mixed and whole blood samples are not hemolytic or previously frozen.
2. Bring samples, the Uni-Gold™ Syphilis Treponemal test devices and all components to room temperature (15-30°C).
3. Remove the required number of devices from their individual foil pouches and lay on a clean, flat surface.
4. Label the device with appropriate patient information.
5. For serum or plasma samples, use the transfer pipette provided (part # 99-8001). Squeeze the transfer pipette midway and place the pipette in the sample to be tested. Draw sample up to the black indication line and remove from sample tube. Touch the end of the pipette onto the bottom of the sample port on the test device and dispense the **entire** volume.
6. For venous whole blood, use 20 µL whole blood.
7. For finger stick whole blood samples, use the capillary tube provided (part # 99-8000). Do not exceed the indicated line. Make sure not to squeeze the bulb. Touch the end of the capillary tube onto the bottom of the sample port and squeeze out the **entire** volume.
8. Add 3 drops of wash buffer to the sample port.
9. Keep the test device on a level surface and incubate at room temperature.

10. Read assay results immediately at the end of the 15 minute incubation. Do not read results after 15 minutes as they may be inaccurate.

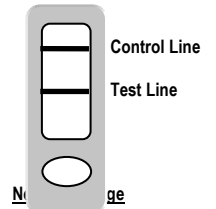
11. Discard device after result is interpreted or if invalid.

INTERPRETATION OF RESULTS

Positive Result

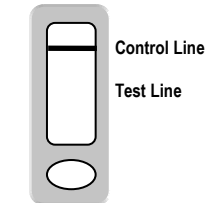
Two pink/red lines of any intensity appear in the device window; at the test line and control line positions. This indicates a reactive result that is interpreted as positive for Syphilis antibodies.

Positive Image



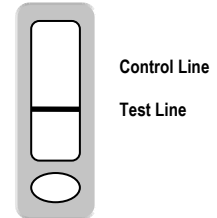
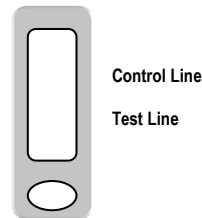
Negative Result

A single pink/red line of any intensity appears in the device window at the control line position. There is no line at the test line position. This indicates a non-reactive result that is interpreted as negative for Syphilis antibodies.



Invalid Result

No line appears in the device window at the control line position. This is an invalid result and cannot be interpreted. This is irrespective of whether or not a pink/red line appears in the device window at the test line position. If either condition below occurs, the test should be repeated with a new device.



The Uni-Gold™ Syphilis Treponemal is a treponemal assay; therefore patients with previously treated Syphilis will be positive on the assay. The test can not distinguish between present and past infection. Any sample giving reactive or equivocal results on initial testing must be supplemented with a quantitative non-treponemal test (such as RPR and VDRL) to distinguish active disease and assist in ruling out false positives.

The following table is used for result interpretation:

Non-Treponemal Result (NT)	Treponemal Result Uni-Gold™ Syphilis Treponemal	Report/interpretation for all except neonates or infants.
Negative	Negative	No serological evidence of infection with <i>T. pallidum</i> , incubating or early primary Syphilis cannot be excluded.
Positive	Negative	Current infection unlikely, probability of biological false positive secondary to other medical conditions such as febrile diseases, immunizations, intravenous drug use, autoimmune diseases, etc. Recommend repeat testing non-treponemal and treponemal by other test method.
Negative	Positive	Probably past infection or potential cross-reactivity with other spirochetes/related antigens. Additional testing appropriate to clinical findings/history. A possibility of false negative non-treponemal (NT) due to prozone and late Syphilis or neurosyphilis.
Positive	Positive	Presumptive evidence of current infection or possibly an inadequately treated infection, persistent infection, reinfection, or biological false positive if prior history. Additional testing consistent with clinical assessment needed.*

Negative	Test not performed	Current infection unlikely. Effectively treated infection if previously diagnosed and treated. Cannot exclude incubating/early primary Syphilis, latent or neurosyphilis.
Test not performed	Negative	Current or past infection is unlikely but cannot exclude incubating or early Syphilis.
*Quantitative non-treponemal testing; clinical history; repeated (sequential) serological testing for changes in titer. HIV-infected individuals may have delayed seroreactivity or negative serology.		

PERFORMANCE CHARACTERISTICS

The performance of Uni-Gold™ Syphilis Treponemal was evaluated on 210 retrospective serum and plasma samples at an external site.

Clinical Sensitivity & Specificity

The sensitivity and specificity of the test was compared against TPPA with retrospective samples as shown in the following table.

Uni-Gold™ Syphilis Treponemal		TPPA	
		+	-
Uni-Gold™	+	134	4
	-	1	71
Total		135	75

Sensitivity: 99.3% (134/135) 95% CI 95.3 – 99.9%
Specificity: 94.7% (71/75) 95% CI 86.2 – 98.3%

Cross Reactivity

The sensitivity of Uni-Gold™ Syphilis Treponemal was further investigated by testing samples from people with unrelated medical conditions, including HIV, Chlamydia, Gonorrhoea and hCG positive samples. There was no significant interference of Uni-Gold™ Syphilis Treponemal observed.

Interfering Substances

Treponemal positive and negative samples were individually spiked with 1800 mg/dL of Human IgG and 1000 mg/dL human serum albumin, human hemoglobin and bilirubin and tested with Uni-Gold™ Syphilis Treponemal.

Samples with elevated levels of triglycerides and cholesterol were spiked with Treponemal positive plasma and were tested by Uni-Gold™ Syphilis Treponemal.

Samples with elevated levels of human serum albumin, hemoglobin, bilirubin, human IgG, triglycerides and cholesterol did not interfere with Uni-Gold™ Syphilis Treponemal test and control lines. These potentially interfering conditions do not affect the performance of Uni-Gold™ Syphilis Treponemal. In addition, several anticoagulants were tested and none were found to affect the performance of Uni-Gold™ Syphilis Treponemal.

Reproducibility Study

Reproducibility testing was carried out on twelve blinded samples (varying positive and negative samples) by two operators, twice daily at each of two sites for five days (40 replicates). 100% of the samples tested for *T. pallidum* antibodies produced the expected results.

REFERENCES

- World Health Organization Technical Report Series. No.674 (1982) Treponemal infections.
- Schroeter A.L., Lucas J.B., Price E.V., and Falcone V.H. (1972). Treatment for early Syphilis and reactivity of serologic tests. *Journal of the American Medical Association*, 221: 471-476.

ORDERING INFORMATION

Cat. No.	Item	Quantity
1206710	Uni-Gold™ Syphilis Treponemal	20 devices
1206711	Uni-Gold™ Syphilis Treponemal Control	1 positive & 1 negative

GUIDE TO SYMBOLS



Consult Instructions for Use

REF

Product Number

LOT

Lot Number

IVD

In Vitro Diagnostic Medical

BUF

WASH

Wash Buffer



Do Not Reuse

Tp

Treponemal



Use By



Caution, consult accompanying documents



Temperature limitation



Manufacturer



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